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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/606,959 | 06/27/2003 | David F. Nicoli | 034515-001 | 4840 |

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT PAPER NUMBER

1743

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/606,959

Applicant(s)

NICOLI ET AL.

Examiner

Maureen M. Wallenhorst

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005 and 21 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1743

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission originally filed on October 21, 2005 has been entered.

2. Claims 2-9, 18-46, 48-58 and 67-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 2 of claim 2, the phrase "said agglomeration" should be changed to –said rate of agglomeration—so as to be consistent with amended claim 1. This same change should also be made on line 2 of claim 8, line 4 of claim 18, line 4 of claim 19, line 3 of claim 20, line 2 of claim 22, line 2 of claim 37, line 2 of claim 38, line 15 of claim 40, line 2 of claim 54, line 2 of claim 56, line 4 of claim 67, line 6 of claim 68, line 5 of claim 69, line 2 of claim 70 and line 2 of claim 71.

On line 2 of claim 43, the phrase "said stress factor level" lacks antecedent basis. This phrase should be changed to –an applied level of said stress factor--.

On line 1 of claim 48, the phrase "wherein said means for detecting said particle agglomeration" should be changed to –said means for detecting an increase in said rate of said particle agglomeration—so as to be consistent with amended independent claim 47.

On line 3 of claim 72, the phrase "each stress factor level" lacks antecedent basis since claims 71 and 47, from which claim 72 depend, do not positively recite different stress factor levels. See this same problem on lines 2-3 of claim 74.

Art Unit: 1743

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-10, 13, 47-59 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Nicoli et al (from American Laboratory, vol. 33(1), January 2001, pages 32-39).

Nicoli et al teach of a method and apparatus for measuring the stability of colloidal suspensions (dispersions of solid or liquid particles suspended in a liquid carrier). Nicoli et al teach that the stability of colloidal suspensions can be analyzed by applying a stress factor to the suspension, such as the addition of excessive amounts of electrolyte to the suspension or by thermal or pH shock (i.e. changing the temperature or pH of the suspension). See the last column on page 34 and the first column on page 39 of Nicoli et al. Nicoli et al teach that these stress factors cause particles in the suspensions to coalesce or agglomerate due to the reduction in the inter-particle electrostatic repulsive forces that confer stability to the emulsion. See the middle column on page 34 of Nicoli et al. Nicoli et al teach that the particle size distribution of a

Art Unit: 1743

colloidal suspension can be measured by analyzing the suspension with a single particle optical sensor (SPOS), which serves to measure both the light diffraction and light scattering of the sample. The technique of single particle optical sensing provides sensitivity to small changes in the large-particle fraction of a colloidal suspension. This sensitivity is required to ascertain the quality and stability of a product. The SPOS technique analyzes particles one at a time to produce a particle size distribution that is constructed directly from each particle. Each particle traverses a flow channel through a ribbon of light. The sensor responds to the particles by measuring both light scattering and light extinction. See page 36 in Nicoli et al. The particle size distribution (PSD) produced includes the concentration of particles as a function of size over a range of normal particle sizes and a distribution of outlier particles comprising the uppermost tail of the PSD. The outlier particles in the tail of the PSD consist of oversized fat globules caused by coalescence of the smaller primary droplets due to reduction of the inter-droplet electrostatic repulsive forces that confer stability to the emulsion.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1743

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 11-12, 14, 18-22, 29-33, 37-40, 60-61, 63 and 67-71 are rejected under 35

U.S.C. 103(a) as being unpatentable over Nicoli et al (from American Laboratory).

For a teaching of Nicoli et al, see previous paragraphs in this Office action.

Nicoli et al fail to teach that changing the pH level or adding electrolyte to a colloidal suspension serves to change or reduce the net charge on the surfaces of the particles in the suspension. However, such a phenomenon would have been obvious to one of ordinary skill in the art at the time of the instant invention since Nicoli et al teach that the stress factors such as pH shock and addition of electrolyte to a colloidal suspension serve to change and reduce the electrostatic repulsion between the particles, thus indicating a change or reduction of the net charge on the surfaces of the particles. Nicoli et al also fail to teach of applying the stress factors to a colloidal suspension in increments at spaced time intervals resulting in increasingly higher stress levels, or of applying different levels of stress factor to different batches of the same colloidal suspension. However, these steps would have been obvious to one of ordinary skill in the art in order to analyze and determine what level of stress factor is required to cause a colloidal suspension to become unstable, and how long/what level of the stress factor must be applied to the colloidal suspension in order to render it unstable. Nicoli et al also fail to teach of calculating the percentage of the dispersed phase (PDP) in the colloidal suspension analyzed from the measured particle size distribution. However, such a step would have been obvious to one of ordinary skill in the art in order to obtain a measure of the stability of the suspension since the greater the percentage of dispersed particles in the suspension, the greater the stability and vice-versa.

Art Unit: 1743

9. Claims 15-17, 34-36 and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicoli et al (from American Laboratory) in view of Friberg et al (submitted in the Information Disclosure Statement filed on September 24, 2003). For a teaching of Nicoli et al, see previous paragraphs in this Office action. Nicoli et al fail to teach that that addition of a salt to a colloidal suspension can be used as a stress factor to measure the stability of the suspension.

Friberg et al teach that the addition of an electrolyte or salt such as sodium chloride to an emulsion causes a reduction in the electric repulsion potential of the particles in the emulsion, and a resulting reduction in the barrier height between the particles. This change with salt concentration results in a loss of stability in the emulsion due to the agglomeration of the particles therein. Friberg et al teach that the change from a stable emulsion to an unstable one takes place at a well-defined salt concentration. See the last half of page 66 in Friberg et al.

Based upon the combination of Nicoli et al and Friberg et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to perform the stability testing method taught by Nicoli et al by adding a salt such as sodium chloride to a colloidal suspension as the stress factor since Friberg et al teach that the addition of a salt to an emulsion serves to render the emulsion unstable by reducing the repulsion potential and the barrier height between the particles, similar to the action of changing the pH or adding an electrolyte to the colloidal suspension.

10. Claims 23-28, 41-46 and 72-77 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests a method and apparatus for measuring the stability of a colloidal

Art Unit: 1743

suspension by applying a stress factor to the suspension, measuring the level of particle agglomeration in the suspension, and calculating a rate of change or an increase of a percentage of the dispersed phase (PDP) in the suspension along with a figure of merit (FM) derived from the calculated rate of change or increase in the PDP.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Nicoli et al (US Patent no. 6,794,671) and the two articles to Driscoll et al which all teach of the agglomeration of particles in emulsions over time that occurs due to the instability of the emulsions.

12. Applicant's arguments filed December 5, 2005 have been fully considered but they are not persuasive.

The previous rejections of the claims under 35 USC 112, second paragraph made in the last Office action mailed on July 5, 2005 have been withdrawn in view of Applicants' amendments to the claims. However, some new rejections under this statute are made above as necessitated by Applicants' amendments to the claims. The previous rejection of the claims under 35 USC 102(b) as being anticipated by Garver et al is withdrawn in view of Applicants' persuasive arguments.

Applicants argue the rejection of the claims under 35 USC 102(b) and 35 USC 103 as being anticipated by or obvious in view of Nicoli et al by stating that Nicoli et al fail to teach of detecting an increase in the rate of particle agglomeration as a measure of the stability of a dispersion or emulsion. In response to this argument, it is noted that "rate" is defined as the quantity, amount or degree of something measured per unit of something else. Figure 4 in the

Art Unit: 1743

Nicoli et al reference measures the rate of particle agglomeration in a fat emulsion since this figure measures the concentration of different sizes of particles in a fat emulsion per unit time (i.e. as a function of time). Nicoli et al teach of measuring the stability of emulsions and dispersions, and stability of an emulsion or dispersion is a measure of how long the emulsion remains resistant to the agglomeration of particles therein. According to the reference to Parfitt submitted in the Information Disclosure Statement filed on October 21, 2005, the stability of a colloidal dispersion is defined as the presence or absence of change in the total number of particles in the dispersion with time. The total number of particles in the dispersion can change over time by particle agglomeration or flocculation. Therefore, since Nicoli et al teach of measuring the amount of particle agglomeration in a dispersion or emulsion with respect to time, and stability of an emulsion or dispersion is determined by a measure of particle agglomeration, Nicoli et al also inherently measure the rate of particle agglomeration as a measure of the stability because rate refers to how fast something occurs over time.

For all of the above reasons, Applicants' arguments are not found persuasive.

Art Unit: 1743

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

June 28, 2005

Maureen M. Wallenhorst

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